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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,424	11/03/2003	David W. Johnson	CALW-004/01US 306562-2009	1511
58349 7590 06/05/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
ROBINSON, KEITH O NEAL				
ART UNIT		PAPER NUMBER		
1638				
MAIL DATE		DELIVERY MODE		
06/05/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/698,424

Applicant(s)

JOHNSON ET AL.

Examiner

KEITH O. ROBINSON

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 6-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's pre-appeal brief conference request, filed August 28, 2008 has been received and entered in full. In the 'Pre-Appeal Brief conference decision' filed April 2, 2009 it has been decided that prosecution for this case will be re-opened and thus, the finality of the rejection of the last Office action, mailed March 31, 2008 has been withdrawn.

2. Applicant's cancellation of claims 1, 5 and 20-29, filed December 12, 2007, have been received and entered in full.

3. Claims 2-4 and 6-19 are under examination.

Claim Objections

4. Claims 16, 18 and 19 are objected to because of the following informalities: The claims should be amended as follows because only a single invention can be claimed.

Claim 16 should read: A seed [Seed] of the alfalfa variety of claim 15 or a regenerable part [parts] of said seed.

Claim 18 should read: A seed [Seed] of an alfalfa plant pollinated by the pollen of claim 17 or a regenerable part [parts] of said seed.

Claim 19 should read: An alfalfa plant produced by the seed of claim 16 or a regenerable part [parts] of said seed.

Appropriate correction is requested.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions.

See MPEP 2163(I) where it states “[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116”.

The specification only provides evidence that Applicant was in possession of alfalfa variety CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and does not provide evidence of

possession of every alfalfa plant with the claimed characteristics as is broadly claimed. Of the above mentioned varieties, only CW 75046, CW 83201, and CW 95026 are disclosed as having improved standability (i.e. more erect stems) and fast recovery after spring green-up or after harvest. Alfalfa variety CW 85029 does not appear to have the claimed traits.

In the instant invention, one of ordinary skill in the art would only recognize that Applicant has invented has only invented alfalfa varieties CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45).

MPEP 2163.02 further states, "[u]nder *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed".

In the instant case, Applicant has conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, Applicant was in possession of alfalfa varieties CW 75046 (see pages 25-29), CW 83201 (see pages 29-35), CW 85029 (see pages 35-39) and CW 95026 (see pages 40-45) and not each and every alfalfa plant with the claimed characteristics as is broadly claimed.

Thus, based on the disclosure of the specification, Applicant has only shown possession of alfalfa varieties CW 75046, CW 83201, CW 85029 and CW 95026.

Applicant has possession of a narrow genetic base and is broadly claiming the phenotype. Applicant is in possession of a narrow invention limited to particular lines; however, they are broadly claiming every alfalfa plant that has the phenotype of their lines even though no analyses as to which genes are involved or how the traits are expressed is given. This is paramount to selecting a seed line for high yield and then claiming every seed line that has high yield, regardless of how they are made. It would be like selecting a seed line for its color and then claiming every seed that happens to have that characteristic regardless of how it was derived.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

7. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to any alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions.

Since the alfalfa variety is essential to the claimed inventions, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of

35 U.S.C. 112 may be satisfied by a deposit of the plant. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. Thus, a deposit is required for enablement purposes. A deposit of 2500 seed of each of the claimed embodiments is considered sufficient to ensure public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

- (d) a test of the viability of the biological material at the time of deposit (see 37 C.F.R. 1.807) and,
- (e) the deposit will be replaced if it should ever become inviable.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Though the specification provides steps on how to make the claimed invention, it is unclear how one skilled in the art would be able to make and use the claimed invention based on the disclosure of the specification.

For example, in the development of alfalfa variety 'CW 75046' the initial step discloses that 1,382 French lines (half-sib families or populations) were seeded into the field at West Salem, WI (see page 25, lines 15-16 of the specification); however, the specification does not provide any guidance regarding any of the 1,382 French lines.

This is important because Bouton (How alfalfa varieties are developed. *In California/Nevada Alfalfa Symposium*, 3-4 December, Reno, NV, 1998) teaches, "[collection and development of parents] is one of the most important decisions in the breeding program because the end product will only be as good as the parents which originally went into the process" (see pages 2-3).

Thus, it is unclear how one skilled in the art would be able to use Applicant's specification to make and use the claimed invention when said invention is produced using uncharacterized material. This lack of guidance is also found in alfalfa variety 'CW 83201' (see page 29, line 14 to page 32, line 8), 'CW 85029' (see page 35, line 8 to page 37, line 22) and 'CW 95026' (see page 40, line 3 to page 42, line 20).

In addition, this lack of guidance would lead to undue experimentation for one skilled in the art to determine which 1,382 French lines, for example, would possess the claimed characteristics that would be used in the method disclosed in the specification to produce the claimed invention.

The development of improved alfalfa varieties is unpredictable. Barnes et al (Alfalfa germplasm in the United States: Genetic vulnerability, use, improvement, and maintenance. USDA Tech. Bull. 1571, 21 pages, 1977) teach that differential attractiveness among alfalfas, plant methods and environmental differences can affect crossing percentages when using bees in natural crossing between two nonbred alfalfa populations (see page 14, third paragraph). Barnes et al also teach that phenotypic selection is effective only for highly heritable characters (see page 15, first paragraph).

In addition, Julier et al (Crop Sci. 40: 365-369, 2000) teach that within-population variation can hinder the rate of improvement for polygenetic traits, including lodging (see page 365, second paragraph).

Given the breadth of the claims, the lack of guidance regarding the use of uncharacterized French lines in the initial step of the methods disclosed in the specification on how to make and use the claimed invention, the amount of

experimentation for one skilled in the art to determine which of the multitude of uncharacterized French lines would possess the claimed characteristics, and the unpredictability of the development of improved alfalfa varieties it would require undue trial and error experimentation for one of skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cluff et al (U.S. Patent No. 6,143,951, November 7, 2000, in view of Bouton et al (Standard tests to characterize alfalfa cultivars, Intensive grazing A-8,

August 1998), in view of Bolanos-Aguilar et al (Crop Sci. 42: 45-50, January/February 2002).

The claims are broadly drawn to any alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions.

Cluff et al teach a *Medicago sativa* alfalfa line, WL-C290, which has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38). Excellent standability is interpreted as high standability as defined on page 14, line 2 of the specification which is equivalent to more erect stem.

Though Cluff et al do not teach calculating the percent faster recovery or more erect stems as claimed in the instant invention, Bouton et al teach measuring plant heights after harvesting. See, for example, 1st column, last paragraph to 2nd column, 1st paragraph of the first page. Bouton et al also teach comparing checks with alfalfa plants that are tolerant to grazing. See, for example, 2nd column, 1st paragraph of the first page. Also, see, for example, Table 1 of the second page where it teaches percent survival by dividing final plant counts by initial plant counts and multiplying by 100. It would have been obvious to one of ordinary skill in the art that other formulas can also be used to select an alfalfa variety having about 8% or greater faster recovery after spring green-up or after harvest.

Though Cluff et al do not teach calculating the percent of erect stems, Bolanos-Aguilar et al teach a lodging scale from 1 (no lodging) to 5 (fully lodged). See, for

example, page 46, 2nd column, 1st paragraph. In addition, Bolanos-Aguilar et al teach that lodging is unfavorable to seed setting, as more compact canopy could limit pollination and possibly induce disease damage to pods. See page 49, 1st column, last paragraph. Thus, it would have been obvious to one of ordinary skill in the art to select plants that have more erect stems. It would have been obvious to one of ordinary skill in the art that other formulas can also be used to select an alfalfa plant having 15% or greater more erect stems.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of the cited references to produce the claimed invention because it would have been obvious that the claimed alfalfa plant can be selected using different selection techniques and formulas.

One of ordinary skill in the art would have been motivated to combine these teachings to produce the claimed invention because plants having 8% or greater faster recovery after spring green-up or after harvest and 15% or greater more erect stems at late bloom compared to adapted commercial varieties grown under the same field growing conditions would be an improvement over the adapted commercial varieties.

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Cluff et al in producing an alfalfa line having very fast recovery after harvest and excellent standability.

Claim Rejections - 35 USC § 102/103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 2-4 and 6-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cluff et al (U.S. Patent No. 6,143,951, November 7, 2000. The claims read on any *Medicago sativa* alfalfa varieties with 8% or greater faster recovery after spring green-up or after harvest

coupled with having 15% or greater more erect stems at late bloom when compared to an adapted commercial check variety.

Cluff et al teach a *Medicago sativa* alfalfa line, WL-C290, that has very fast recovery after harvest and excellent standability under sprinkler irrigation (see column 17, lines 37-38). Excellent standability is interpreted as high standability as defined on page 14, line 2 of the specification which is equivalent to more erect stem.

Cluff et al do not teach calculating the percent faster recovery or more erect stems; however, one of ordinary skill in the art would understand that an alfalfa plant with faster recovery after harvest and more erect stems would possess these characteristics even if one of ordinary skill in the art did not use the measuring and calculating techniques in steps (b)(1-6) and (c)(1-5) of claim 15.

The alfalfa plant taught by the prior art differs from the claimed alfalfa plant only in their method of making, namely by the use of different parental material in the prior art. However, the method of making the claimed alfalfa plant would not distinguish it from the prior art alfalfa plant.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to

Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Conclusion

15. No claims are allowed.

Contact Information

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH O. ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson

/David H Kruse/

Primary Examiner, Art Unit 1638

4 June 2009